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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 10 19 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,693

Applicant(s)

MIHARA ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on *11 July 2002*.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s) _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Claims 16-25 are pending in the present application.

The text of those sections of Title 35 U.S.C. Code not included in this action can be found in a prior Office Action.

Claim Objections

Claims 17, 19-20, 22, 24-25 are objected to because of the following informalities: The term "Claim" on the first line of each claim should not be capitalized. Appropriate correction is required.

Written description

Claims 16, 18-19, 21 and 23-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

Applicant's invention is drawn to a method for producing xylitol or D-xylulose from glucose utilizing a bacterium belonging to the family *Acetobactereacea* located between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or a bacterium belonging to the genus *Asaia*, and more specifically belonging to *Asaia ethanolifaciens*. Applicant's invention is also drawn to a method for producing xylitol or D-xylulose from glucose utilizing a bacterium belonging to the family *Acetobactereacea* located between *Gluconobacter oxydans subsp. Oxydans* and *Acetobacter aceti* or a bacterium belonging to the genus *Zucharibacter*, and more specifically belonging to *Zucharibacter floricola*. The specification identifies and characterizes five microbial strains that have the ability to produce xylitol or D-xylulose from glucose in cell cultures, four of which (S877, S1009, S1019 and S1023 strains) are designated in a new genus *Zucharibacter floricola* and the other (P528 strain) is assigned to a new genus *Asia ethanolifaciens* by the Applicants. The instant claims embraced a method for producing xylitol or D-xylulose from glucose using any bacterium belonging to a particular new family or genus designated by Applicants, including those that have not yet been naturally isolated. Apart from the functional limitation of producing xylitol or D-xylulose from glucose, there is no common core structure or elements that are shared between the strains P528, S877, S1009, S1019 and S1023 identified in the instant specification to a broad genus of bacterium encompassed by the instant claims. There is also no apparent relationship between the possession of SEQ ID NO:1 or any one of SEQ ID NOs: 2, 3, 4 or 5 by an

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isolated bacterial strain with the recited characteristics or phenotype (an ability to produce xylitol or D-xylulose from glucose). The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants' filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). Since the five isolated microbial strains disclosed in the instant specification represent only a small portion of the total number of strains in the family or in the genus being claimed, Applicants have not possessed a representative number of species of strains to describe the broad genus or a family that is being utilized in the claimed methods. Particularly, the identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia ethanolifaciens* or *Asaia*. The phenotype of one strain from a species of a genus of thousands of bacteria is not representative of the genus as a whole, let alone the family of *Acetobacteraceae* located between *Acetobacter methanolicus* and *Acetobacter pasteurianus*.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.*

Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed July 11, 2002 in Paper No. 8 (pages 4-6) have been fully considered.

Applicants argue that the claimed invention relates not to a microorganism itself, but rather relates to the use of a microorganism that has the ability to produce xylitol or D-xylulose from glucose. Additionally, Applicants argue that the possibility that unisolated strains may be included in the claims could not be a basis of denying fulfillment of written description. Applicants' arguments are respectfully found unpersuasive because at the effective filing date of the present application, Applicants have not possessed a representative number of species of bacterial strains belonging to the family Acetobacteraceae located between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or the family Acetobacteraceae located between *Gluconobacter oxydans* subsp. and *Acetobacter acetii* or the genus *Asaia* or the genus *zucharibacter* to practice the methods as claimed. The identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia ethanolifaciens* or *Asaia*. The phenotype of one strain from a species of a genus of thousands of bacteria is not

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representative of the genus as a whole, let alone the family of *Acetobacteraceae* located between *Acetobacter methanolicus* and *Acetobacter pasteurianus*. Similarly, the four disclosed microbial strains from *Zucharibacter floricola* do not fairly represent a broad spectrum of the genus because these microbial strains could all be clustered at one end of the spectrum for such a genus, let alone representing the claimed family *Acetobacteraceae* located between *Gluconobacter oxydans* subsp. *Oxydans* and *Acetobacter aceti*. It is noted that the method claims require essential or critical elements, for this instance representative microbial species representing the broad genus and family recited in the claims, which are not adequately described in the specification and which are not conventional in the art as of Applicants' filing date. Additionally, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants argue that the molecular taxonomy limitation based on the sequence comparisons of 16S rRNA in claims 16 and 21 as well as the microbiological characteristics in claims 17 and 22 are structural limitations and not functional limitations. Examiner noted that the structural characteristics that are in claims 17 and 22 are not recited in other claims, therefore the bacterium utilized in the methods recited in other claims does not have to possess the structural characteristics in claims 17 and 22. Merely reciting using molecular taxonomic analysis and by comparison of the 16S RNA gene nucleotide sequences (there is no requirement for any RNA gene nucleotide

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sequence comparison between the bacterium in claim 21 with other known sequences), does not indicate which relevant identifying characteristics that the bacterium recited in the claims possess. For example, what are the structural characteristics of the 16S RNA gene nucleotide sequence possessed by the bacterium, so that it can be classified in the family, genus recited in the claims, and not in others?

Applicants further argue "Since a homology of 16S rRNA indicates a relation of microorganisms, it is easily assumed that the microorganisms showing homology in 16S rRNA share similar phenotype. Therefore, it is considered that there is, in fact, correlation between the molecular taxonomy based on the sequence of 16S rRNA and phenotype". Applicants' argument is respectfully found unpersuasive because there is no factual evidence indicating that there is a correlation between the molecular taxonomy based on the sequence of 16S rRNA and the desired phenotype (for this instance, the ability to produce xylitol or D-xylulose from glucose). Applicants clearly state "it is easily assumed that the microorganisms showing homology in 16S rRNA share similar phenotype". Please note the terms "assumed" and "similar phenotype" (not necessarily the same phenotype).

Accordingly, claims 16, 18-19, 21 and 23-24 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth above.

Claim Rejections - 35 USC § 112

Claims 16-19 and 21-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing xylitol or D-

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xylulose from glucose in a cell culture using the isolated microbial strains P528, S877, S1009, S1019 and S1023, does not reasonably provide enablement for other embodiments in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 16-19 are drawn to a method for producing xylitol or D-xylulose from glucose utilizing a bacterium belonging to the family *Acetobacteraceae* which is located between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or a bacterium belonging to the genus *Asaia*, and more specifically *Asaia ethanolifaciens*.

Claims 21-24 are directed to a method for producing xylitol or D-xylulose from glucose utilizing a bacterium belonging to the family *Acetobacteraceae*, which is located between *Gluconobacter oxydans subsp. Oxydans* and *Acetobacter aceti* or a bacterium belonging to the genus *Zucharibacter*, and more specifically *Zucharibacter floricola*.

The specification teaches the isolation and partial characterization of isolated microbial strains P528, S877, S1009, S1019 and S1023. Among the 3000 strains isolated and cultured, the aforementioned strains possess the biochemical characteristics or properties as claimed (e.g., producing xylitol or D-xylulose from glucose in cell cultures). The specification further teaches that upon analysis of the 16 rRNA nucleotide sequences for the isolated strains P526 and S877, and partial 16 rRNA sequencing analysis for strains S1009, S1019 and S1023, coupled with multiple alignment and evolution distance calculation for the obtained sequences with analogous bacterial sequences available from databases, a molecular phylogenetic tree was

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established. As a result, the strain P528 was identified as a new species belonging to the genus *Asaia*, and provisionally designated by Applicants as *Asaia ethanolifaciens* sp. nov. The strains S877, S1009, S1019 and S1023 were all identified as microorganisms of a new species belonging to a new genus, and provisionally designated by Applicants as *Zucharibacter floricola* gen. No., sp. nov. The above evidence has been noted and considered. However, the evidence is not reasonably extrapolated to the instant broadly claimed invention for the following reasons.

The instant claims encompass the utilization of any bacterium belonging to the family *Acetobacteraceae* which is located between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or between *Gluconobacter oxydans* subsp. *Oxydans* and *Acetobacter aceti* or those having the broad properties or characteristics recited in claims 18 and 22 for producing xylitol or D-xylulose from glucose in cell cultures. The instant specification is not enabled for such a broadly claimed invention partly for the reasons already set forth in the lack of Written Description Section above. Briefly, the instant specification fails to provide sufficient guidance for one skilled in the art to isolate a representative number of species of strains, or genus of related species having the desired properties or characteristics to be utilized in the methods as claimed. Apart from the disclosure of a single isolated bacterial strain P528 newly designated to *Asaia ethanolifaciens* and four closely related bacterial strains S877, S1009, S1019 and S1023 newly designated to *Zucharibacter floricola*, neither the prior arts at the effective filing date of the present application nor the instant specification provide sufficient guidance for the make and use of other related bacterial species or related genus

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having the desired characteristics. It is unclear whether the four disclosed microbial strains from *Zucharibacter floricola* represent a broad spectrum of the genus or that they are all clustered at one end of such a genus, let alone representing the claimed family *Acetobacteraceae* located between *Gluconobacter oxydans* subsp. *Oxydans* and *Acetobacter aceti*. The identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia ethanolifaciens* or *Asaia*. The phenotype of one strain from a species of a genus of thousands of bacteria is not representative of the genus as a whole, let alone the family of *Acetobacteraceae* located between *Acetobacter methanolicus* and *Acetobacter pasteurianus*. In addition, the instant specification fails to provide sufficient teachings regarding to a reproducible screening process capable of identifying large numbers of bacterial strains having the desired characteristics belonging to the claimed family representing numerous groups of related species or genera. Moreover, it is also unclear whether the soil collected from the bank of Tama river contains a sufficient number of related bacterial species to represent the family or genera encompassed by the scope of the instant claimed invention. In the absence of such teachings, it would have required undue experimentation for a skilled artisan to practice the full scope of the instant broadly claimed invention, particularly with regard to the amount of experimentation required to screen a large number of bacterial strains for the claimed family, genera and to characterize them for the desired characteristics.

With respect to the breadth of the presently claimed invention, Applicants are directed to the decision *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

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It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

Additionally, the courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel*.).

As written, because of the phrase "culturing a bacterium having an ability to produce xylitol or D-xylulose from glucose" the instant claims are not limited to a method for producing xylitol or D-xylulose from glucose in cell cultures using naturally isolated bacterial strains having endogenous desired properties. However, apart from this teaching, the instant specification offers no guidance for a skilled artisan on how to make and use a bacterium having any ability (e.g., through a recombinant technology) to produce xylitol or D-xylulose from glucose in cell cultures other than what is disclosed in the specification. In the absence of sufficient guidance provided by the present specification, it would have required undue experimentation for a skilled artisan to make and use the methods as claimed. This part of the rejection can be obviated if Applicants simply recite culturing an isolated microbial strain P528, S877, S1009, S1019 or S1023 having the ability to produce xylitol or D-xylulose from glucose.

Accordingly, due to the lack of guidance provided by the specification, the quantity of experimentation necessary, the state of the prior art, the and the breadth of

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the claims, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed July 11, 2002 in Paper No. 8 (pages 6-7) have been fully considered.

Applicants argue mainly that the present invention relates not to a microorganism itself, but relates to use of a microorganism which has the ability to produce xylitol or D-xylulose from glucose, and therefore one skilled in the art can produce xylitol or D-xylulose from glucose using the bacterial strains of the present invention. Applicants' arguments are respectfully found to be unpersuasive because the instant specification fails to provide sufficient guidance for one skilled in the art to isolate a representative number of species of strains, or genus of related species having the desired properties or characteristics to be utilized in the methods as claimed. In the absence of the availability of representative number of species of strains or genus of related species, it would have required undue experimentation for a skilled artisan to practice the full scope of the instant broadly claimed invention, particularly with regard to the amount of experimentation required to screen a large number of bacterial strains for the claimed family, genera and to characterize them for the desired characteristics. Additionally, the courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel*.).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16 and 21, the phrase "molecular taxonomic analysis" is vague and it renders the claim indefinite because it is unclear what are the specific molecular taxonomic parameters or criteria used and in which particular phylogenic software programs utilized for the analysis to locate the bacterium of claim 16 between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or the bacterium of claim 22 between *Gluconobacter oxydans* subsp. *Oxydans* and *Acetobacter aceti*. Since there are no fixed standards, the metes and bounds of the instant claims are not clearly determined.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed July 11, 2002 in Paper No. 8 (page 7) have been fully considered.

Applicants argue that the concept and methodology of molecular taxonomic analysis would be clear to one skilled in the art, and that such analysis clearly defines the metes and bounds of the claimed subject matter. Applicants' argument is respectfully found unpersuasive because it is still unclear what are the specific

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molecular taxonomic parameters or criteria used and in which particular phylogenetic software programs utilized for the analysis to locate the bacterium of claim 16 between *Acetobacter methanolicus* and *Acetobacter pasteurianus* or the bacterium of claim 22 between *Gluconobacter oxydans* subsp. *Oxydans* and *Acetobacter aceti*. Since there are no fixed standards, the metes and bounds of the instant claims are not clearly determined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-25 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,335,177. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass all the embodiments of claim 6 in the issued Patent No. 6,335,177.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER